

## REMARKS

Claims 1 and 52 have been amended. Claims 1-23 and 49-73 are pending in this application. No new matter is added to the application as apparent from the nature of the present claim amendments.

### I. Claim Rejections – 35 U.S.C. § 103

Claims 1-11, 14-23, and 49-73 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (US Pat. Appln. No. US2002/0077592 A1) in view of Adair et al. (US Pat. 6,211,904) in further view of Mauze et al. (US Pat. 6,375,627).

This rejection is respectfully traversed, at least due to the following:

1. The claims are further amended herein in the manner that was discussed in the telephone interview of July 16, 2010, to indicate that the sensor is not an image *sensing* device (based on the comments in the Office Action clarifying the Examiner's position that Adair et al. employs an image *sensing* device, not an image *recording* device) and, thus, are allowable at least for reasons as discussed in Applicant's Response dated September 15, 2010, to the previous Office Action;
2. The proposed combination of Barry, Adair et al. and Mauze et al. would not have been obvious to one of ordinary skill in the art, because the Examiner's proposed reason for combining Barry and Adair et al. (to provide a surgeon an observation and measurement of where the stent is within the vasculature) would be circumvented by the Examiner's further proposal to combine Mauze et al. therewith (to use Mauze et al.'s physiological condition sensors that do not allow observing a stent's position in place of Adair et al.'s endoscope tool); and
3. Mauze et al.'s sensors are fixed within a needle body structure that is located external to the patient, for analyzing fluid withdrawn from the patient and, thus, Mauze et al. provide no teaching or suggestion of positioning a sensor moveable relative to the catheter and the stent, and extending the sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent.

### **1. The Claims Are Further Amended Per Telephone Interview Discussion**

The claims are further amended herein in the manner that was discussed in the telephone interview of July 16, 2010. In particular, claims 1 and 52 are amended to indicate that the sensor is not an image *sensing* device, based on the comments in the Office Action clarifying the Examiner's position that Adair et al. employs an image *sensing* device, not an image *recording* device.

More specifically, Applicant's Response dated September 15, 2010, responded to the previous Office Action in the manner that had been discussed with the Examiner in the telephone interview of July 16, 2010. In the noted interview, Applicant understood the Examiner as having stated that the claims would be allowable over the prior art of record, if amended to recite that the sensor is not a device that records images. Accordingly, the claims were previously amended in that manner.

However, in the Office Action dated April 11, 2011, the Examiner states a position that Adair discloses a sensor other than an image *recording* sensor, since it is simply an *image sensor* (not necessarily recording). Accordingly, to expedite an allowance of the claims, Applicant further amends claims 1 and 52 to recite that "the sensor is not an image sensing device" (i.e., replacing the term "recording" with "sensing"). The present claim amendments are fully consistent with the agreements reached in the above-mentioned interview and the Examiner's comments in the recent Office Action regarding "image recording sensor" (versus "image sensor"). Applicant requests an allowance of the claims, as further amended herein, at least for reasons as discussed in the above-mentioned interview (and in Applicant's Response of September 15, 2010).

### **2. The Proposal To Combine Mauze With Barry And Adair Circumvents The Examiner's Purported Reason To Combine Barry and Adair**

The proposed combination of Barry, Adair et al. and Mauze et al. would not have been obvious to one of ordinary skill in the art. In particular, the Examiner's proposed reason for

combining Barry and Adair et al. (to provide a surgeon an observation and measurement of where the stent is within the vasculature) would be circumvented by the Examiner's further proposal to combine Mauze et al. therewith (to use Mauze et al.'s physiological condition sensors that do not allow observing a stent's position in place of Adair et al.'s endoscope tool).

More specifically, in the Office Action dated April 11, 2011, the Examiner raises the above-quoted new rejection by citing the U.S. Patent 6,375,627 to Mauze et al., in combination with previously cited references to Barry and Adair et al. Applicant had already addressed rejections based on the Examiner's proposed combination of the Barry and Adair et al. references, in Applicant's Appeal Brief of November 8, 2008. The present claims are patentably distinguished from Barry and Adair et al., at least for reasons as expressed in Applicant's Appeal Brief, as well as the telephone interview of July 16, 2010, discussed in Applicant's previous response.

In addition, the Examiner's proposed reason for combining Barry and Adair et al. would be circumvented by the Examiner's further proposal to combine Mauze et al. therewith. Accordingly, the Examiner has failed to raise a prima facie case of obviousness with regard to the rejection based on the proposed combination of Barry, Adaire et al. and Mauze et al.

More specifically, the Examiner acknowledges (on page 4 of the Office action) that Barry does not disclose "extending a sensor . . . through the stent to a position located outside of the catheter and outside of the stent." (Office Action, page 4, lines 3-6.)

However, the Examiner states that "Adair et al. teaches that it is known to use the step of extending the sensor through the stent to a position located outside of the catheter and outside of the stent." (Office Action, page 4, lines 7-14.) The Examiner contends that it would have been obvious to modify Barry per the cited disclosures of Adair, "for providing the surgeon an observation and measurement of where the stent is within the vasculature on a low profile device." (Office Action, page 4, line 18 to page 5, line 5.)

The Examiner's proposed combination of Barry and Adair et al. still does not teach or suggest the invention recited in claim 1. As acknowledged by the Examiner, Barry and Adair do not disclose a sensor that is not an image recording device or an electrochemical, biological or

oxygen type sensor. (Office Action, page 5, lines 13-15.) In that regard, the Examiner cited Mauze et al. and argued that it would have been obvious to modify the system taught by Barry in view of Adair et al. with an electrochemical, biological, oxygen type sensor as taught by Mauze et al. (Office Action, page 5, lines 18-21.)

However, it would not have been obvious to further modify the Examiner's proposed combination of Barry and Adair et al., to replace Adair et al.'s endoscope with electrochemical, biological or oxygen sensors, because doing so would then be contrary to the Examiner's reasoning for combining Barry and Adair et al. in the first place.

As noted above, the Examiner argues that it would have been obvious to modify Barry per the cited disclosures of Adair et al., "for providing the surgeon an observation and measurement of where the stent is within the vasculature on a low profile device." (Office Action, page 4, line 18 to page 5, line 5.) Adair et al. uses an endoscope (image sensor) to allow a surgeon to visually observe a stent location.

However, the Examiner's further argument to further modify Barry and Adair et al. (to combine Mauze et al. with Barry and Adair et al.) would involve using Mauze et al.'s physiological sensors instead of Adair et al.'s endoscopic image sensor. Doing so would, then, circumvent the Examiner's purported purpose of combining Adair et al. with Barry in the first place (i.e., to allow the surgeon to visually observe where the stent is located within the vasculature). In that regard, it is submitted that the proposed combination of Barry, Adair et al. and Mauze et al. would not have been obvious to one of ordinary skill in the art.

It is submitted that the Examiner has not presented a prima facie case of obviousness, because the Examiner's purported reason for combining Barry and Adair et al. (to visually observe stent placement via an endoscopic image sensor) would be circumvented by the Examiner's further proposal to modify that combination with Mauze et al.'s physiological sensors (to use Mauze et al.'s physiological sensors for Adair et al.'s image sensor). Indeed, there is no teaching, suggestion or motivation for one of ordinary skill in the art to have combined the Barry, Adair et al. and Mauze et al. references in the manner proposed by the

Examiner. Accordingly, the rejection of independent claims 1 and 52 is further respectfully traversed.

**3. There Is No Teaching, Suggestion Or Motivation For Combining Mauze's Fixed, External Physiological Sensors With Barry and Adair**

Mauze et al.'s sensors are fixed within a needle body structure that is located external to the patient, for analyzing fluid withdrawn from the patient and, thus, Mauze et al. provide no teaching or suggestion of positioning a sensor moveable relative to the catheter and the stent, and extending the sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent.

It would not have been obvious to one of ordinary skill in the art to combine Mauze et al. with Barry and Adair et al., as proposed in the rejection. Mauze et al. describe a fluid extraction device with sensors located external to the patient's body (for analyzing fluid extracted from the patient, in an environment that is external to the patient). More specifically, Mauze et al. describe a sampling needle 10 that has a shaft portion 14, a plate portion 16 and an internal channel 20. The shaft portion 14 has a sharp tip 18 for puncturing a patient's skin. (Mauze, col. 3, lines 12-17 and Fig. 1.)

It is clear from Mauze et al.'s description, that the plate portion 16 of the needle 10 remains outside of the patient. Sensors 24-27 are fixed on the plate portion 16 of the sampling needle 10, at a location that remains external to the patient. The sensors 24-27 remain in fixed positions relative to the needle 10. Fluid drawn out from a patient flows through the needle channel 20 and passes the sensors 24-27 on its way toward a proximal opening 23 of the channel 20. (Mauze, col. 4, lines 54-56.)

Mauze et al.'s needle 10 is moveable within a shell 30, to selectively expose the pointed tip 18. However, the sensors 24-27 always remain in fixed positions relative to the needle 10, on the plate portion 16 of the needle 10. The sensors 24-27 are arranged for sensing fluid inside of the needle (fluid passing through the interior channel 20 of the needle 10). There is no teaching or suggestion in Mauze et al. of the method recited in claim 1, including "positioning a sensor moveable relative to the catheter and the stent, wherein the sensor is not an image sensing

device” and “extending the sensor, relative to the catheter and the stent, through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent.” (Underlines added for emphasis.)

Instead, Mauze et al.’s teaching of sensors 24-27 that are fixed to a plate portion 16 of an extraction sample needle 10 is completely inconsistent with a method in which a sensor is moveable and extended through a catheter and stent to a position located outside of the catheter and stent. Because Mauze et al. describe sensors 24-27 mounted at fixed positions inside of a needle channel (where the needle channel is located external to the patient), one skilled in the art would not have considered Mauze et al. as teaching or suggesting a modification to Barry or Adair et al. to position sensors 24-27 moveable relative to a catheter and a stent, or to extend those sensors through a lumen in the catheter and through a stent to a position located outside of the catheter and outside of the stent. Accordingly, it is respectfully submitted that Mauze et al. would not have taught or suggested to one of ordinary skill in the art to modify Barry and Adair with Mauze et al.’s fixed-to-the-needle sensors.

Accordingly, the rejection of independent claims 1 and 52 is yet further respectfully traversed.

#### **4. Dependent Claims**

Each of claims 2-11, 14-23, 49 and 53-73 is dependent (directly or indirectly) on one of base claims 1 and 52. Accordingly, each of those dependent claims is distinguished from the references of record, including Barry, Adair et al. and Mauze et al., at least for reasons as discussed above with respect to base claims 1 and 52, as well as for additional reasons apparent from the language of those dependent claims.

Claims 12 and 13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Adair et al. and further in view of Silver (U.S. Pat. 6,442,423). Claims 4 and 19-23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Adair et al. Each of those rejections is respectfully traversed.

Each of claims 4, 12, 13, and 19-23 is dependent (directly or indirectly) on base claim 1. Accordingly, each of those dependent claims is distinguished from the references of record, including Barry, Adair et al. and Mauze et al., at least for reasons as discussed above with respect to base claim 1, as well as for additional reasons apparent from the language of those dependent claims.

Furthermore, as Mauze et al. was not included in the rejections of claims 4, 12, 13 and 19-23, those claims are further distinguished from Barry and Adair et al. for reasons as discussed in Applicant's Appeal Brief of November 5, 2008 (incorporated herein by reference) and as discussed during the telephone interview of July 16, 2010 (referenced in Applicant's previous Response). Moreover, it is noted that the Examiner acknowledges (as discussed above) that neither Barry nor Adair et al. teach a sensor that is not an image sensing device. Accordingly, claims 4, 12, 13 and 19-23 are further distinguished from Barry and Adair et al. (considered alone or in the combination proposed by the Examiner).

With regard to claims 12 and 13, the Silver reference does not address the above-noted distinctions of base claim 1 over Barry and Adair et al.

The Examiner acknowledged that Barry and Adair et al. do not disclose a sensor sensing an analyte or glucose. However, the Examiner cited Silver as employing a glucose sensor. The Examiner argued that it would have been obvious to modify the method taught by Barry in view of Adair with a sensor for sensing an analyte for providing means to monitor and control glucose levels. (Office Action, page 5, lines 12-18.) However,

Silver describes sensor 20 affixed to a stent 14. The sensor 20 is attached to and held/supported by the stent 14. Because Silver's sensor 20 is fixed to the stent 14, Silver provides no teaching or suggestion of "positioning a sensor moveable relative to the catheter and the stent, wherein the sensor is not an image sensing device" and "extending the sensor, relative to the catheter and the stent, through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent." Silver's teaching of supporting the sensor 20 by fixing it to the stent 14 would have taught one of ordinary skill in the art away from the claimed method, including positioning a sensor moveable relative to a stent and extending the

sensor through the stent to the outside of the stent. Furthermore, it would not have been obvious to modify the Examiner's proposed combination of Barry and Adair et al.'s to employ Silver's sensor 20 in place of Adair et al.'s endoscope. In particular, the Examiner's purported reason for combining Barry and Adair et al. (to visually observe stent placement via an endoscopic image sensor) would be circumvented by the Examiner's further proposal to modify that combination with Silver's sensor in place of Adair et al.'s endoscope. Accordingly, it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine Barry, Adair et al. and Silver in the manner proposed in the rejection of claims 12 and 13.

Accordingly, the rejections of claims 4, 12, 13 and 19-23 are also respectfully traversed.

## **II. Conclusion:**

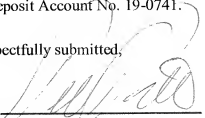
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: July 11, 2011  
FOLEY & LARDNER LLP  
Customer Number: 90319  
Telephone: (213) 972-4500  
Facsimile: (213) 486-0065

By:   
Ted R. Rittmaster  
Attorney for Applicant  
Registration No. 32,933